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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,852	12/10/2003	Frederick L. Hall	14230-010002	4628

20985 7590 02/26/2008
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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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02/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/733,852	Applicant(s) HALL ET AL.	
	Examiner REGINA M. DEBERRY	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-69 and 72-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66,67 and 72-80 is/are rejected.
- 7) ☒ Claim(s) 68 and 69 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment filed 21 November 2007 has been entered in full. Claims 66-69 and 72-80 are pending and under examination.

Withdrawn Objections And/Or Rejections

The rejection to claims 66, 72-80 under 35 U.S.C. 102(e) as being anticipated by Oppermann et al., US Patent Application Publication No. 2005/0250936 A1, as set forth at pages 2-3 of the previous Office Action (28 August 2007), is *withdrawn* in view of the amendment (21 November 2007).

The rejection to claims 76, 78-80 under 35 U.S.C. 112, second paragraph, as set forth at pages 3-4 of the previous Office Action (28 August 2007), is *withdrawn* in view of the amendment (21 November 2007).

The rejection to claim 80 under 35 U.S.C. 112, first paragraph, enablement, as set forth at pages 4-5 of the previous Office Action (28 August 2007), is *withdrawn* in view of the amendment (21 November 2007).

Claim Rejections - 35 USC § 102(e)

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 66, 67, 72-74, 76-78 and 80 are rejected under 35 U.S.C. 102(e) as being anticipated by Ishikawa et al., United States Patent Application Publication US 2002/0102709 A1.

Ishikawa et al. is entitled to priority of continuation-in-part application no. 09/507,691, filed 2/22/00, for the disclosure relied upon. The instant application claims and is entitled to priority of 09/624,874, filed 7/21/00, for the present claims. The instant application is not entitled to priority back of provisional application no. 60/145,488 filed on 7/21/99, for the present claims.

Ishikawa et al. teach a collagen-binding active polypeptide. A peptide from fibronectin is ligated to a physiologically active peptide and this hybrid polypeptide is provided with both the collagen-binding activity and the physiological activity. Ishikawa et al. teach that the collagen-binding activity/physiologically active protein is useful as a drug delivery system (abstract and paragraphs 0001, 0039, 0115 and 0196). Ishikawa et al. teach that cytokines, growth factors and other physiological active peptides are expected for their use as a pharmaceutical. Ishikawa et al. teach a collagen binding active polypeptide ligated to either insulin (paragraphs 0066, 0190 and claims) or nerve growth factor (NGF)(paragraph 0190). Ishikawa et al. teach that the term “physiologically active peptide” denotes activities such as growth, differentiation, migration and synthesis of biological substances (paragraph 0191) (**applies to claims 66, 67 and 80**). Ishikawa et al. teach the gene coding for the collagen-binding activity and physiologically active protein. Ishikawa et al. teach recombinant vectors, prokaryotic cells and methods of making the recombinant hybrid polypeptide. Ishikawa et al. teach that the collagen-binding/physiologically active protein is well-adapted for industrial production by bacteria and that production in yeast,

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insect cells or animal cells is also acceptable (paragraphs 0083-0092 and 0195)(**applies to claims 72-74, 76-79**).

Claim Rejections - 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al., as applied to claims 72 and 74 above, and further in view of Oppermann et al., (reference of record, US Patent Application Publication No. 2005/0250936 A1)

The teachings of Ishikawa et al. are described above. Ishikawa et al. do not teach retroviral vectors comprising the polynucleotide encoding the fusion polypeptide.

Oppermann et al. claims and is entitled to priority of 09/375,333, filed 8/16/99, for the disclosure relied upon. Oppermann et al. teach that the TGF beta superfamily includes inhibin

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(paragraphs 0003 and 0027). Oppermann et al. teach inhibin alpha and beta (paragraph 0057). Oppermann et al. teach fusion proteins comprising TGF beta superfamily members and a collagen binding domain and nucleic acids encoding the fusion proteins. Oppermann et al. teach the use of retroviral vectors, host cells and methods of making recombinant proteins (paragraphs 0133, 0138, 0139, 0142-0146).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of producing a collagen-binding/physiological active protein as taught by Ishikawa et al. by using a retroviral expression vector as taught by Oppermann et al. with a reasonable expectation of success. The motivation and expected success is provided by the general knowledge to one skilled in the art that retroviral expression vectors can be used to efficiently transfect (infect) animal cells to make recombinant proteins.

Claim Objections

Claims 68 and 69 are objected to because they depend from a rejected claim.

Conclusion

Claims 66, 67, 72-80 are rejected.

Claims 68 and 69 are objected to.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to REGINA M. DEBERRY whose telephone number is (571)272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RMD
2/15/08

/Manjunath N. Rao, /
Supervisory Patent Examiner, Art Unit 1647